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| 10/840,090 | 05/06/2004 | Keith T. Carron | UW-2 | 7838 |
| 28581 7590 07/30/2908 DUANE MORRIS LLP PO BOX 5203 | | | EXAMINER | |
| | | | MUI, CHRISTINE T | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/840.090 CARRON ET AL Office Action Summary Examiner Art Unit CHRISTINE T. MUI 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 May 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-17 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-17 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Response to Arguments

- Applicant's arguments, see REMARKS, filed 14 May 2008, with respect to drawings have been fully considered and are persuasive. The objection of drawings has been withdrawn.
- Applicant's arguments, see REMARKS, filed 14 May 2008, with respect to claim 16 have been fully considered and are persuasive. The rejection of claim 16 has been withdrawn.
- 3. Applicant's arguments, see REMARKS, filed 14 May 2008, with respect to the rejection(s) of claim(s) 1-17 under 35 USC 102(b) and 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.
 However, upon further consideration, a new ground(s) of rejection is made in view of

Drawings

1. The drawings were received on 14 May 2008. These drawings are entered.

Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

USP 5,255,067 to Carrabba et al.

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1-2, 11-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,255,067 to Carrabba et al (herein referred 'Carrabba').

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3. Regarding claims 1, 11-14 and 16, the reference Carrabba discloses a substrate that has a metallic phase that possesses the specific geometry, chemical and electromagnetic properties required to enhance emission of Raman signal frequencies of adsorbed molecules. An apparatus is provided that includes a monochromatic light source, a means to transmit the desired wavelength from the light source to the surface of the substrate and means for collecting the scattered Raman signal frequencies and transmit them to a detector to analyte the recorded response. The metallic phase of the substrate can be comprised of a SERS-active metal such as Aq, Au or Cu prepared in a high surface area morphology. A porous layer may be added to enhance the adsobancy of the molecular species. The metals that are used for the metallic phase have a microroughness on the 1-50 nanometer scale, interpreted by the examiner to be a surface comprising of at least one nanoparticle and having a roughness that mimics the size and shape of a nanoparticle. Furthermore, colloidal suspensions of Ag or Au particles 5-20 nanometer of diameter show SERS activity that are suitable on the substrate for analysis. The SERS active surface can also be prepared by first exposing the surface to a physical or chemical vapor deposition to enhance the roughness of the surface. In an alternative embodiment of the substrate, the SERS-active metal and the adsorbing/reacting layer are interpenetrating, one dispersed within each other so that upon application of a sample, the sample is exposed to the metal surface and the adsorbing surface for the detection of a species simultaneously (see abstract, column 3, lines 40-coumn 4, line 62). It is interpreted by the examiner that in the embodiment where the metal and adsorbing layers are interpenetrating, the sample is exposed to the Application/Control Number: 10/840.090 Page 4

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metal surface and adsorbed to the metal surface for further analysis by Raman scattering, if the chemical is present in the sample fluid administered to the metal surface.

4 Regarding claim 2, the reference Carrabba discloses the SERS-active metal is covered by a second material that functions as an adsorbant and/or reactant for the molecular species to be detected. The second material may be a porous layer used to enhance adsobancy, which in turn enhances the already surface enhanced Raman scattering metal surface (see abstract, column 3, lines 42-49).

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2 Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- Claims 3-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrabba.
- 9. Regarding claims 3-9, the reference Carrabba discloses in preparing the substrate with an underlying SERS-active metal surface, a second adsorbing or reacting layer, which is the oxide of the underlying metal layer. The deposition on the underlying SERS-active metal surface the coating is to have a proper composition and/or morphology to render it active. In some cases, silver oxide is known to exist in two oxidation states that can be interconverted electrochemically. The SERS-active roughened Ag surface can be oxidized electrochemically and oxidation state may be specified by the electropotential of oxidation. AgO may be an oxidizing agent for some gas phase material, while Ag₂O may have reducing properties toward other gaseous moieties. A variety of oxides may be prepared as coating materials which react with oxidizable molecules. The products by the reaction are typically a lower oxide and adsorbed molecular oxidation products. The adsorbing or reactive need not be an oxide of the SERS-active metal surface, but may also be organic polymers that are spread with adsorptive properties and may be generated on the roughened metal substrates by electropolymerization, dipping or casting, photopolymerization and plasma

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polymerization. The second layer may be organic or inorganic compounds with specific adsorptive or reactive properties toward a gas phase species of interest (see column 4, line 64-column 6, line 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the additive in the second layer to be an oxidizing agent, organic or inorganic polymers to treat the surface so that the additive that acts sacrificially, acts as an intermediate with one chemical, causes the surface to be more surface enhanced, acts as a stabilizer or as a sacrificial agent to prevent the metal surface from being dissolved to modify the purpose of the second layer before the sample adsorbed to the metal surface if present in the sample for the determination of a species using Raman scattering.

- 10. Regarding claim 15, the reference Carrabba discloses the claimed invention except for where the nanoparticle is provided in a lyophilized colloidal form. Carrabba discloses a colloidal suspensions of Ag or Au particles that are prepared on the SERS-active surface (see column 4, lines 45-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nanoparticles that is provided in a lyophilized colloidal form, so that the metal surface comprises of a biological substance that is reactive to a biological sample, such as tissue, blood or serum, to reveal the presence or absence of an analyte.
- Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over
 Carrabba as applied to claim 1 above, and further in view of WO 98/59234 to Carron et
 (herein referred "Carron").

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12. Regarding claim 17, the reference Carrabba discloses the claimed invention except for where the chemical species is cyanide. Carron discloses a method for the detection of a controlled substance where a sensor is coated with molecules on a spectroscopic surface, such as silver, copper or other appropriate metal surfaces. Carron discloses a modifier that can be attached to some aspect of the coating to achieve a desired result to serve to reserve a position on the molecule to react with the controlled substance or analyte involved. Cyanide may be used in a reversible fashion that forms an adduct which results from the covalent bonding on the surface of the spectroscopic surface that aids in the detection of an analyte or a controlled substance (se page 31, lines 12-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the chemical to be cyanide so that one will be able to detect the presence or absence of cyanide in a sample fluid.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Jill Warden/ Supervisory Patent Examiner, Art Unit 1797